Small Electric Drive. Compact and powerful system for use in hand and foot surgery.

User's Manual

SYNTHES® Power Tools

Instruments and implants approved by the AO Foundation

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Introduction

General Information

Intended use
The Small Electric Drive is designed for use in general traumatology, especially hand and foot applications involving surgical procedures such as drilling, burring, reaming, pin and wire placement, cutting of bone and hard tissue.

Safety instructions
The Small Electric Drive is only to be used for patient treatment after careful consultation of the instructions for use.

The Small Electric Drive is designed for use by physicians and trained medical personnel.

DO NOT use any component if damage is apparent.

DO NOT use any component if the packaging is damaged.

DO NOT use this equipment in the presence of oxygen, nitrous oxide or a mixture consisting of flammable anesthetics and air.

To ensure the proper operation of the tool, only use Synthes original accessories.

Before the first and every subsequent use, power tools and their accessories/attachments have to run through the complete reprocessing procedure. Protective covers and foils must be fully removed before sterilization.

For the tool to function properly, Synthes recommends cleaning and servicing it after each use in accordance with the process recommended in the chapter "Care and Maintenance". Compliance with these specifications can considerably extend the service life of the tool. Only use Synthes oil (519.97) to lubricate the tool.

Efficiently working cutting tools are the basis for successful surgery. Therefore, it is mandatory to check used cutting tools after every use for wear and/or damage and to replace them if necessary. We recommend using new Synthes cutting tools for every surgery. Cutting tools must be cooled with irrigation liquid to prevent heat necrosis.

The user of the product is responsible for proper use of the equipment during surgery.

If the Small Electric Drive is used in conjunction with an implant system, make sure to consult the corresponding "Technique Guide".

For important information regarding electromagnetic compatibility (EMC), please refer to the chapter "Electromagnetic Compatibility" in this manual.

The tool is classified as type B against electrical shock and leakage current. The tool is suitable for use on patients in accordance with IEC 60601-1.

To ensure the proper operation of the tool, Synthes recommends annual maintenance by a Synthes service center. The manufacturer shall assume no responsibility for damage resulting from improper operation, neglected or unauthorized maintenance of the tool.

Caution:
- To avoid injuries, the locking mechanism of the tool has to be activated before every manipulation and before placing the tool back down, i.e. the adjustment sleeve has to be in the LOCK position 🔒.
- Should the machine drop on the floor and have visible deffects, do not use it anymore and send it to the Synthes service center.

Accessories/scope of delivery
The main components of the Small Electric Drive (SED) are the handpiece, console and electric cables as well as attachments and accessories. An overview of all the components belonging to the Small Electric Drive can be found in the chapter "Ordering Information".

For the system to operate properly, only Synthes cutting tools should be used.

Special auxiliaries such as cleaning brushes and Synthes oil are available for cleaning and servicing the system. No oils from other manufacturers must be used. Only Synthes oil (519.97) must be used.

Lubricants with other compositions can cause jamming, can have a toxic effect or can have a negative impact on the sterilization results. Only lubricate the power tool and the attachments when clean.

Synthes recommends the use of the specifically designed Synthes Vario Cases (68.001.252 and 68.001.253) and of the specifically designed Synthes Washing Basket (68.001.630) to sterilize and store the system.

The following components are essential to ensure proper operation:
– Small Electric Drive (05.001.175)
– Console (05.001.000, 05.001.002)
– At least one attachment of the system

Please refer to the end of these Instructions for Use for an overview of the components of the system.

Storage and transport
Please use the original packaging for dispatch and transport. If this is no longer available, please contact the Synthes office.

Warranty
The warranty for the tools and accessories does not cover damage of any kind resulting from improper use, damaged seals or improper storage and transport. The manufacturer does not accept liability for damage resulting from repairs or maintenance carried out by unauthorized sites.

Explanation of the general symbols used

Caution
Read the provided Instructions for Use before operating the device.

Consult the Instructions for Use before operating the device.

The device is classified as type B against electrical shock and leakage current. The device is suitable for use on patients according to the standards defined by CSA 601.1, IEC 60601-1 and UL 60601.

Do not immerse device in liquids.

The marked device shall only be used within a specified temperature range.

With regard to electrical shock, fire, mechanical hazards, only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1

The device meets the requirements of directive 93/42/EEC for medical devices. It is authorized by an independent notified body for which it bears the CE symbol.

The European directive 2002/96/EC on waste electrical and electronic equipment (WEEE) applies to this device. This device contains materials that should be disposed of in accordance with environment protection requirements. Please observe national and local regulations. See section entitled “Disposal” on page 39.

Do not reuse
Products intended for single use must not be reused.

Reuse or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness or death.

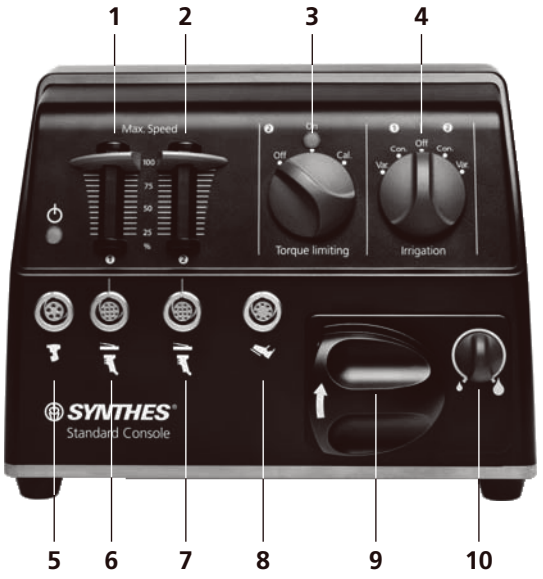
Furthermore, reuse or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in the injury or death of the patient or user.

Synthes does not recommend reprocessing contaminated products. Any Synthes product that has been contaminated by blood, tissue and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Even though they may appear undamaged, the products may have small defects and internal stress patterns that may cause material fatigue.

General Description

The Small Electric Drive (05.001.175) can be supplied with the Standard Console or as an alternative with the Basic Console (without torque limiting function and irrigation).



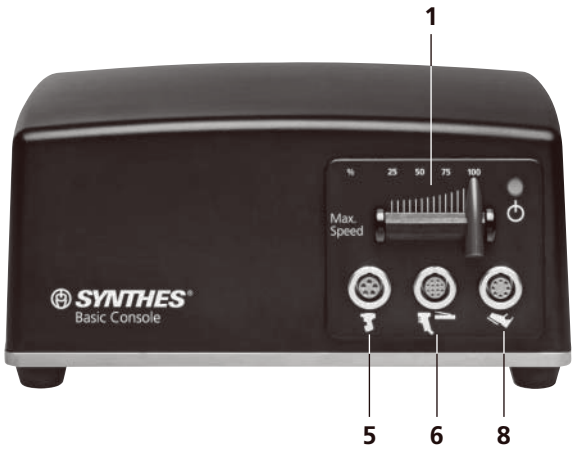
Standard Console with irrigation (05.001.000)

1 Slide control for adjusting the maximum speed for 1
2 Slide control for adjusting the maximum speed for 2
3 Selection switch for torque limiting
4 Selection switch for irrigation
5 Connection for Adapter for Small Battery Drive
6 Connection for Electric Pen Drive and Small Electric Drive 1
7 Connection for Electric Pen Drive and Small Electric Drive 2
8 Connection for Foot Switch
9 Twist lock for irrigation pump
10 Adjustment knob for irrigation flow rate

For more detailed information about the irrigation, please refer to the Electric Pen Drive Manual (J6374).

Basic Console (05.001.002)

1 Slide control for adjusting the maximum speed for
5 Connection for Adaptor for Small Battery Drive
6 Connection for Electric Pen Drive and Small Electric Drive
8 Connection for Foot Switch



Notes:

– The Slide controls for maximum speed adjustment can only be used with the Electric Pen Drive.
– When returning the console for repair or maintenance, always return the power cord.
– Only the consoles having an SED symbol below the connection can be used with the Small Electric Drive. Other consoles can be sent back to the local Synthes service center for an update. Please contact your local representative for further information.

Set-up

Before the initial operation of the device, make sure that the power switch **12** is set to position 0 (OFF). Only connect the console to the power supply with the cable provided via the power plug socket **13** and set the power switch to position 1 (ON). The LED marked with ⏻ on the front of the console signals the proper operation of the console. If the LED flashes, the console must be sent in for maintenance.

A potential equilization connector **14** for an equipotential earth plug is integrated in the console. Existing equipotential earth plugs can be connected there. To increase patient safety, the use is recommended; but according to IEC 60601-1 3rd, it is not mandatory.

Mounting cables on the consoles
To mount the respective cables on the consoles, position the nose on the plugs flush with the groove on the plug sockets and insert the plugs. For improved orientation, red dots are provided on the plug and socket that must face upward when connecting the cable.

Removing cables
To remove the plug, grasp the release sleeve, pull back and remove.

The connections 5 – 8 (page 4) are used to connect the following devices:

(**5**): Connection for a Small Battery Drive handpiece

(**6** and **7**): Connections for an Electric Pen Drive or a Small Electric Drive

(**8**): Connection for the Foot Switch

Connections that are not in use can be sealed off with the protective caps provided.

Caution:
- Do not place consoles directly against a wall, as the console's ventilation will be impaired. Maintain a distance of at least 3 cm.
- Only place consoles on smooth surfaces.
- Do not lay textiles or objects under the console. These can be sucked up and block the ventilation inlet.
- Do not hang irrigation liquid directly above the console in order to prevent liquid from dripping onto the console.
- Do not pull on the cable! Always activate the release sleeve.
- The use of HF (high frequency) equipment for tissue coagulation can cause electromagnetic disturbances – in this case, the cables should be separated as far as possible.

General Description

1 Trigger for speed regulation
2 Trigger for switching to reverse/oscillating drilling
3 Attachment coupling
4 Release buttons for attachment
5 Adjustment sleeve
6 Lock slide
7 Cable IN/OUT
8 LOCK
9 ON
10 OSC DRILL

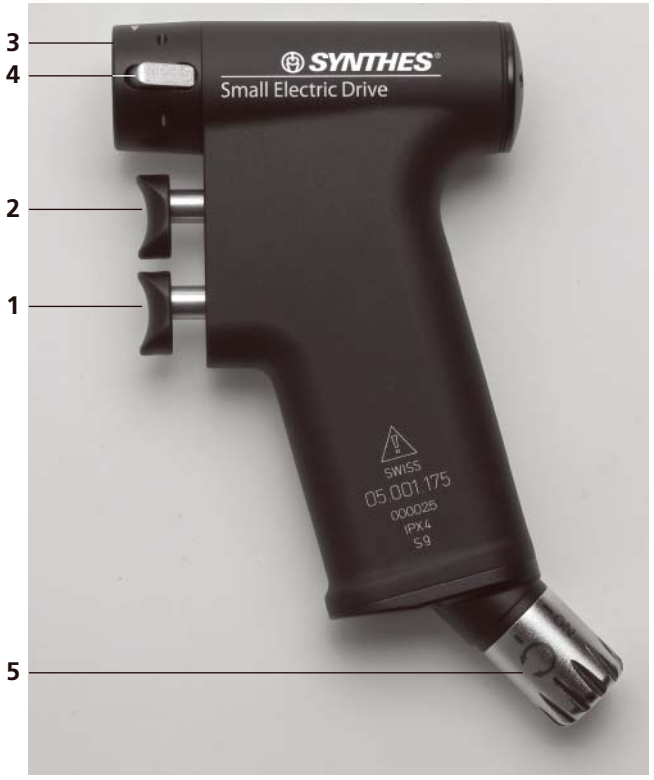


Figure 1

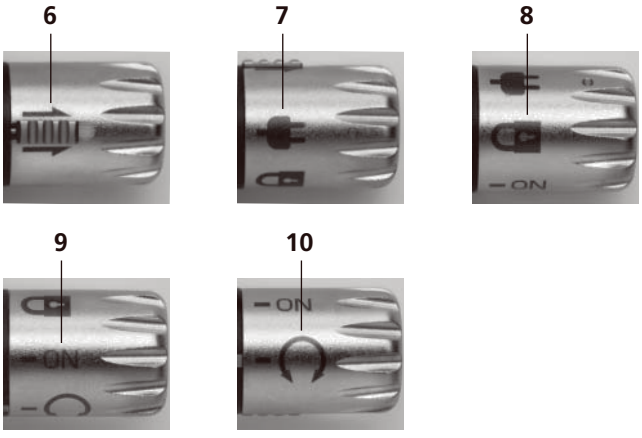
Protective systems
The Small Electric Drive is equipped with a thermal overload safety system that shuts off the tool if it becomes too hot during use. After it cools, the tool can be used again.

Mounting cable on handpiece
Move the adjustment sleeve (**5**) on the handpiece into the position Cable IN/OUT (**7**) by pushing the lock slide (**6**) in the direction indicated by the arrow and by simultaneously turning the adjustment sleeve (**5**) to the desired position.

To insert the plug, you can either align the groove on the plug with the notch in the sleeve or align the symbol present both on the sleeve and on the plug (Fig. 2).

Once the plug is inserted, push the lock slide (**6**) in the direction indicated by the arrow and rotate the adjustment sleeve simultaneously into the LOCK position (**8**). The cable is now firmly locked in the handpiece and the handpiece is in locked mode.

Figure 2



To remove, push the lock slide (**6**) in the direction indicated by the arrow, rotate the adjustment sleeve (**5**) into the Cable IN/OUT position (**7**) and remove the cable.

Speed and rotational direction control

Adjustment sleeve in the ON position
By turning the adjustment sleeve into the ON position (**9**), the handpiece can be set to a clockwise running direction. When pressing on the bottom trigger, the tool starts running in this clockwise direction. When the bottom and top triggers are pressed at the same time, the tool immediately switches to reverse motion. When the bottom trigger is released, the tool immediately stops.

Adjustment sleeve in the OSC DRILL position ( )
When the bottom and top triggers are pressed at the same time, the tool immediately switches to oscillating rotation. When the top trigger is released, the tool returns to normal forward rotation.

In addition to locking the cable, the LOCK position (**8**) is also used for a safety switch-off when changing attachments and tools and before laying it down. This prevents the accidental start-up of the unit while performing these activities.

For instructions on mounting the attachments, see page 10.

Important:
- Never place the Small Electric Drive on a magnetic surface since the machine might start unintentionally.
- Always check its functioning before use.
- Pay particular attention to all the instructions in the individual sections that are identified with "Caution".
- Components that are no longer useful must be disposed of in accordance with the local and national regulations.
- Always wear personal protective equipment (PPE) including safety goggles when working with the Small Electric Drive system.

General Information

The Small Electric Drive System offers a broad range of attachments.

A wide range of rotating attachments has color-coded rings, so that they can easily be identified. The table on the next page lists the different types of attachments available, the color coding as well as the speed of each attachment.

Mounting the attachments
Insert the attachment into the attachment coupling (Fig. 1). If the positioning pins do not lock into place right away, twist the attachment a bit to the right or left until it locks into the correct position. Check if the attachment is seated correctly by gently pulling on it.

Removing the attachments
Press the attachment release buttons (**4**, see Fig. 1 on page 8) simultaneously and remove the attachment from the coupling.

Figure 1

Caution:
- To prevent injury, the power tool must be switched off with the safety system (see page 9) during each manipulation.
- Only use original attachments and tools from Synthes. Damage that arises from using attachments and tools made by other manufacturers is not covered by the warranty.
- Never use an attachment in reverse mode with an old flexible shaft as this could cause serious injury to the patient.

	Article	Product	Speed	Color coding
Drill Attachments	05.001.250	AO Quick Coupling	1120 rpm	Blue
	05.001.252	Chuck (Drilling Speed), with Key, clamping range up to Ø 4.0 mm	1120 rpm	Blue
	05.001.253	Chuck (Drilling Speed), with Key, clamping range up to Ø 7.3 mm	1120 rpm	Blue
Screw Attachments	05.001.251	Screw Attachment with AO Quick Coupling	285 rpm	Red
Ream Attachments	532.017	AO Quick Coupling for Medullary Reaming	285 rpm	Red
	532.018	Hudson Quick Coupling for Medullary Reaming	285 rpm	Red
	532.019	Trinkle Quick Coupling for Medullary Reaming	285 rpm	Red
	532.020	Trinkle Quick Coupling, modified, for Medullary Reaming	285 rpm	Red
	532.015	Quick Coupling for DHS/DCS triple reamers	285 rpm	Red
	05.001.254	Chuck (Reaming Speed), with Key, clamping range up to Ø 7.3 mm, with reverse motion	285 rpm	Red
Other Rotating Attachments	532.011	Mini Quick Coupling	3050 rpm	None
	532.012	J-Latch Coupling	3050 rpm	None
	05.001.186	Quick Coupling for Kirschner Wires	770 rpm	None
	05.001.187	Burr Attachment	15000 rpm	None
	511.30	Radiolucent Drive	3050 rpm	None
Saw Attachments	532.021	Oscillating Saw Attachment	15000 rpm	None
	532.023	Oscillating Saw Attachment II (Crescentic Technique)	15000 rpm	None
	532.026	Oscillating Saw Attachment, large	15000 rpm	None
Other Attachments	511.773	Torque Limiter, 1.5 Nm, for AO Quick Coupling	–	None
	511.776	Torque Limiter, 0.8 Nm, for AO Quick Coupling	–	None
	511.777	Torque Limiter, 0.4 Nm, for AO Quick Coupling	–	None

Technical data is subject to tolerances. Specifications are approximate and may vary from one device to another or as a result of power supply fluctuations.

Drill Attachments

AO Quick Coupling (05.001.250)
For tools with an AO coupling shaft.

Mounting and removing the tools
Insert the tool into the attachment from the front applying slight pressure and turning slightly. It is not necessary to operate the coupling sleeve of the attachment.

To disconnect, push the coupling sleeve of the attachment back and remove the tool.

Chucks
There are two Drill Attachments Chucks available as Drill Attachments for the Small Electric Drive system.

	Clamping range	Spare key	Comments
05.001.252	0–4.0 mm	310.93K	For drilling
05.001.253	0–7.3 mm	510.19	For drilling

Inserting cutting tools
Open the jaws of the chuck using the appropriate key or by hand. Insert the shaft of the tool into the open drill chuck and close it by twisting the chuck. Make sure that the shaft lies central to the three jaws. Tighten the drill chuck with the key. Make sure that the teeth of the key engage correctly in the toothed rim of the chuck.

Removing cutting tools
Open the chuck with the key and remove the tool.

Caution:
- Do not use the Small Electric Drive for acetabular reaming.
- Check the cutting tool for wear and/or damage after each use and replace if necessary.
- To ensure good fixation of the tools, make sure the toothed rims on the drill chuck and key are not worn.

Screw Attachments

AO Screw Attachment (05.001.251)

Mounting and removing the tools

Insert the tool into the attachment from the front by applying slight pressure and turning slightly. It is not necessary to operate the coupling sleeve of the attachment.

To disconnect, push the coupling sleeve of the attachment back and remove the tool.

Caution:

- Care should be taken when inserting screws with the drive unit.
- Never fully insert screws with the drive unit. The final turns or locking should always be done manually.
- Always use an appropriate torque limiting attachment when putting locking screws into a locking plate.
- Theoretically, it is also possible to use the AO Quick Coupling (05.001.250) to insert screws. However, the Screw Attachment (05.001.251) has a lower speed and a higher torque and is therefore more suitable. Screws with a large diameter may not be able to be inserted with the AO Quick Coupling as the torque may not suffice.
- The attachment is also suitable for application at a lower rpm and/or higher torque.

Ream Attachments

Quick Couplings for Medullary Reaming

532.017 AO Quick Coupling
532.018 Hudson Quick Coupling
532.019 Trinkle Quick Coupling
532.020 Trinkle Quick Coupling, modified

The Quick Couplings for Medullary Reaming enable the use of flexible shafts with the appropriate coupling geometry. Reverse motion, which can damage the flexible shafts, is prevented by a special mechanical system.

Inserting cutting tools into the coupling

Maneuver the unlocking ring on the attachment backward and insert the tool (such as a drill bit) while rotating it slightly until it locks into place. Release the ring. Check if the tool is seated correctly in the coupling by gently pulling on it.

Removing cutting tools

Push the unlocking ring on the attachment backward and remove the tool.

Caution:

- Do not use "Quick Couplings for Medullary Reaming" for acetabular reaming. They may only be used for medullary reaming.
- Check the cutting tool for wear and/or damage after each use and replace if necessary.

Quick Coupling for DHS/DCS Triple Reamers (532.015)

For DHS/DCS Triple Reamers; can also be used to open the medullary cavity with most of the Synthes nailing systems.

Mounting and removing the tools

To connect the tool, push the coupling sleeve forward and then introduce the tool while turning slightly. To disconnect, push the coupling sleeve of the attachment forward and remove the tool.

Chucks

There is one chuck available as a Ream Attachment for the Small Electric Drive system.

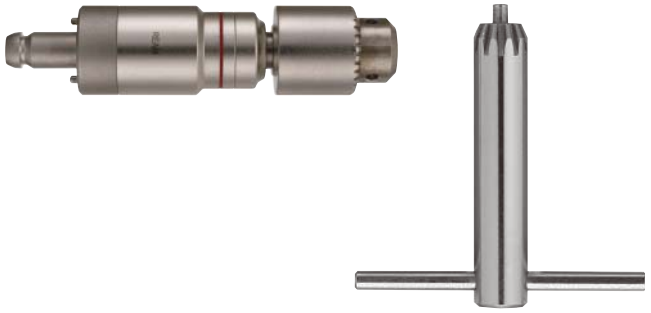
	Clamping range	Spare key	Comments
05.001.254	0–7.3 mm	510.19	For drilling and medullary reaming, with reverse motion

Inserting cutting tools

Open the jaws of the chuck using the appropriate key or by hand. Insert the shaft of the tool into the open drill chuck and close it by twisting the chuck. Make sure that the shaft lies central to the three jaws. Tighten the drill chuck with the key. Make sure that the teeth of the key engage correctly in the toothed rim of the chuck.

Removing cutting tools

Open the chuck with the key and remove the tool.



Caution:

- Do not use the Small Electric Drive for acetabular reaming.
- Check the cutting tool for wear and/or damage after each use and replace if necessary.
- To ensure good fixation of the tools, make sure the toothed rims on the drill chuck and key are not worn.
- Use the Chuck with reverse motion (05.001.254) only with tools that are approved for such use. Otherwise, the tool may break with subsequent damage.

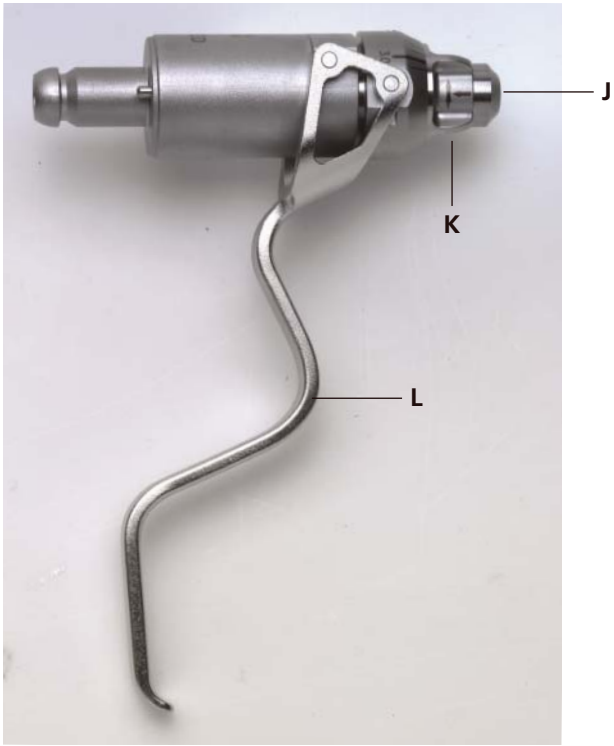
Other Rotating Attachments

Mini Quick Coupling (532.011),
J-Latch Coupling (532.012)
Accepts mini quick coupling or Stryker J-latch drill bits.

Mounting and removing the tools
To connect the tool, pull the coupling sleeve back and then introduce the tool while rotating slightly.
To disconnect, push the coupling sleeve of the attachment back and remove the tool.

Quick Coupling for Kirschner Wires (05.001.186)
Kirschner Wires of any length with a diameter of 0.6 – 3.2 mm can be used with the Quick Coupling for Kirschner Wires.

1. Adjust the Kirschner Wire diameter according to the label on the adjusting sleeve **K**. Slightly press the adjusting sleeve axially against the handpiece and rotate the sleeve.
2. Apply a slight amount of pressure to insert the Kirschner Wire from the front or back into the cannulation **J**. The wire is held automatically.
3. Adjust the working length by pulling on the wire.
4. To affix the wire, pull the tension lever **L** against the tool with your little finger and ring finger. Only pull the tension lever against the tool as much as necessary. The clamping force can be varied by pulling and releasing the clamping lever.
5. Insert the wire into the bone. Apply the clamping force as long as the wire is advanced.
6. To adjust the grip on the wire, reduce the clamping force and move the tool to the desired length. Reclamp the wire by pulling on the tension lever.



Radiolucent Drive (511.30)
The Radiolucent Drive can be used with the Small Electric Drive in combination with the AO Quick Coupling (05.001.250) and the Adapter for the Radiolucent Drive (532.031).

Coupling the Radiolucent Drive to the power tool
Connect the AO Quick Coupling to the Small Electric Drive and the adapter to the Quick Coupling. Position the Radiolucent Drive as far as it will go over the Quick Coupling and the adapter and rotate it into the desired working position. Support the drive with your free hand.

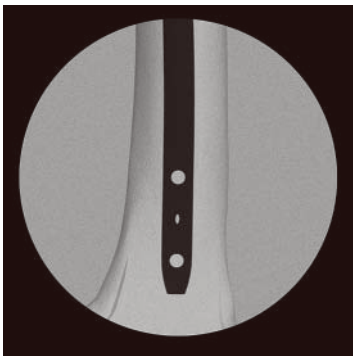
05.001.250 532.031 511.30

Inserting the drill bit
Pull the ring on the attachment forward and position the drill bit inside the coupling as far as it can go while rotating it slightly. Engage the ring on the attachment back in order to fix the drill. Check if the drill bit is seated correctly by gently pulling on it.

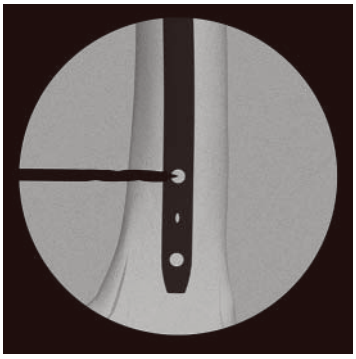
Removing the drill bit
Follow the same procedure in reverse order.

Using the Radiolucent Drive

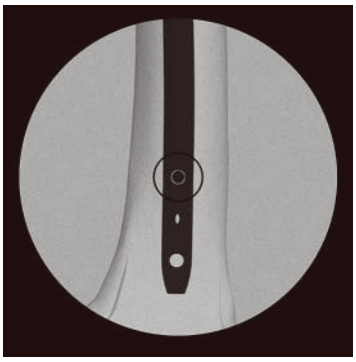
Before positioning the Radiolucent Drive, align the image intensifier until the distal locking hole of the medullary nail is round and easily visible.



After the incision, position the Radiolucent Drive and center the drill bit tip over the locking hole. On the monitor of the image intensifier, you can see both the drill bit and the target rings of the drive.



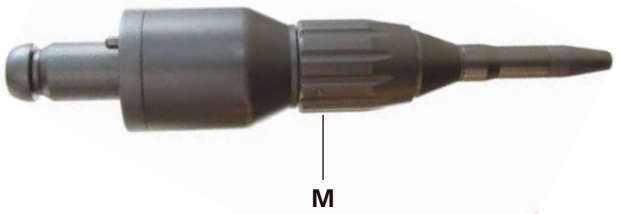
Swing the drive up and center it precisely so that the drill bit appears as a round point and the locking hole is visible around it. The target ring also assists the centering. The locking hole can now be drilled directly.



Caution:

- Grip the coupled Radiolucent Drive tightly when switching on the power tool, particularly if the power tool is held face down.
- Only special 3-flute spiral drill bits can be used. Your Synthes representative will be glad to provide you with additional information on which drill bits can be used.
- Handle the Radiolucent Drive with great care. Do not allow contact between the drill bit and the medullary nail.
- Depending on the setting of the image intensifier, a zone may appear in the rear of the Radiolucent Drive that is not radiolucent. However, this does not inhibit aiming and working with the device.
- To protect the gears, the Radiolucent Drive is equipped with a slip clutch that disengages in case of an overload and emits an audible rattling noise.
- The following procedures can cause an overload:
  - Correcting the drilling angle when the cutting edges of the drill bit are completely in the bone.
  - Hitting the nail with the drill bit.
- Drilling can continue after making the following corrections:
  - Correcting the drilling angle: Remove the drill bit until the flutes are visible and then restart the drilling.
  - Hitting a nail: Remove the drill bit until the flutes are visible and re-aim the drill bit or exchange the drill bit if necessary.

Burr Attachment (05.001.187)
The Burr Attachment is size M. It can be used with Burrs for Burr Attachments of the Electric Pen Drive and Air Pen Drive systems. It is compatible with burr types M and L, but it is recommended to use burrs of size M.



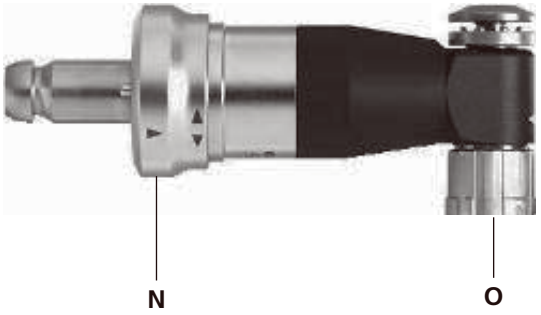
Changing burrs
1. Lock unit.
2. Turn the release sleeve for burrs (**M**) until it engages in the UNLOCK position and remove the tool.
3. Insert the new tool as far as possible, turn it slightly until it locks in place and then turn the release sleeve for burrs into the LOCK position until it engages. The burr is correctly clamped when the marking M on the burr shank is no longer visible.

Information on handling burrs
Synthes recommends using a new sterile burr for each operation. This prevents health risks to the patient.
Used burrs present the following risks:
– Necrosis due to excess heat
– Longer cutting time due to reduced performance of the burr

Caution:
– Burrs must be cooled with irrigation liquid to prevent heat necrosis.
– The attachments may only be used with the burrs intended for this purpose or one size above (attachment is size M, please therefore only use burrs of size M or L).
– Synthes recommends wearing protective goggles when working with burrs.

Saw Attachments

Caution: Even if lines and measurements are indicated on the saws, these articles should not be used as measuring instruments.



Oscillating Saw Attachment (532.021)

Positioning the saw attachment

The attachment can be locked in eight different positions (45° steps) when coupled: Lock the machine, push the sliding sleeve **N** toward the saw blade coupling and rotate the attachment into the desired position (Fig. 1).

Caution: To prevent injury, always grip the saw attachment with the inserted saw blade from the direction of the machine.

Changing the saw blade (Fig. 2)

1. Lock the machine.
2. Pull the locking knob **O** down and turn it counterclockwise.
3. Lift and remove the saw blade.
4. Use a slight amount of pressure to insert the new saw blade and turn it to the desired position. The desired positions can be offset from each other at 45° angles.
5. Place your thumb on the saw blade coupling to hold the saw blade and turn the locking mechanism clockwise until the saw blade is fixed.
6. Unlock the power tool.

Figure 1

Figure 2

Positioning the saw blade
The saw blade can be adjusted in the desired position vertically and horizontally at an angle of 45° (see the earlier sections "Positioning the saw attachment" and "Changing the saw blade").

Using the oscillating saw attachment
The saw blade must already be oscillating when the saw is applied to the bone. Do not apply strong pressure to the saw blade as this will delay the cutting process and the saw teeth will catch in the bone. Optimal saw performance is achieved by moving the power tool slightly back and forth in the plane of the saw blade so that the blade oscillates beyond the bone on both sides. Very precise cuts can be made when the saw blade is guided steadily. Imprecise cuts arise due to used blades, excess pressure or jamming the saw blade.

Instructions for handling the saw blades
Synthes recommends using a new blade for each operation to ensure that the saw blade is optimally sharpened and clean. The following risks are associated with used blades:
– Necrosis caused by excessive heat build-up
– Infection caused by residue
– Extended cutting time due to poor saw performance

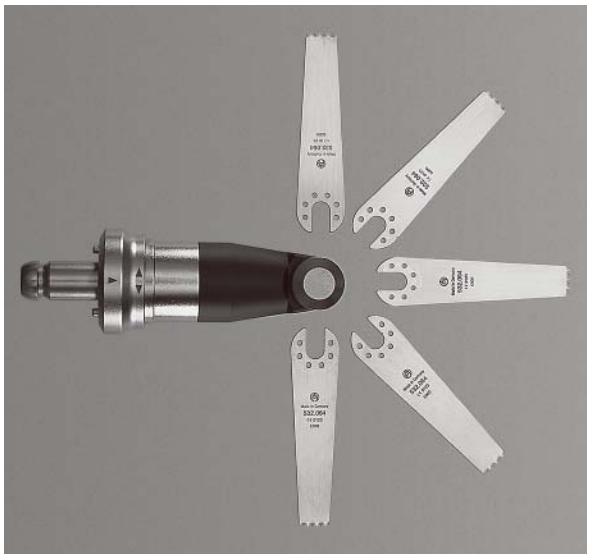
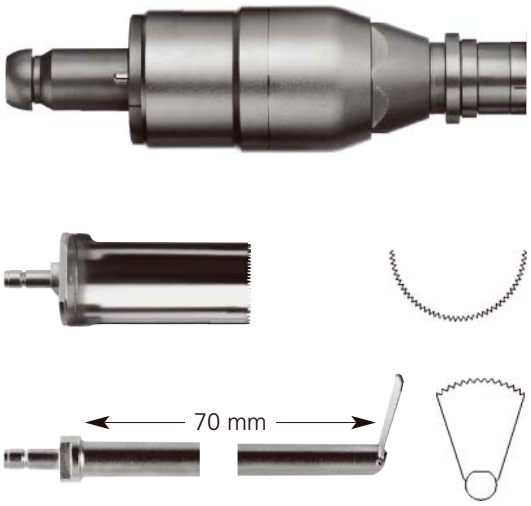


Figure 3

Oscillating Saw Attachment II (Crescentic Technique) (532.023)

The Oscillating Saw Attachment II is essentially designed for use with semicircular saw blades (for example 03.000.313S) guided by a 1.6 mm Kirschner Wire. It can also be used with saw blades with a shaft extension (for example 03.000.340S) for reaching difficult-to-access sites.



Inserting the saw blade

Pull the saw blade coupling toward the handpiece and insert the saw blade while rotating it slightly until it locks into the saw attachment coupling. Release the saw blade coupling and check that the saw blade is correctly fixed by gently pulling on the saw blade.

Removing the saw blade

Pull the saw blade coupling towards the handpiece to release the saw blade.

Caution:

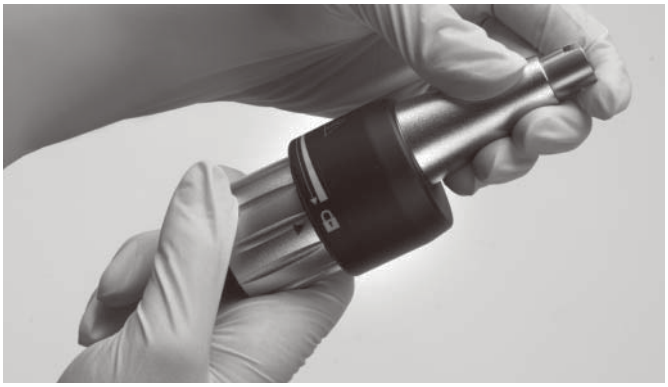
– The saw attachments may only be used with the handpiece in the ON mode. Never use the attachments in OSC DRILL mode (☊).
– The appropriate surgical technique (J9091) should be observed to ensure the safe and successful application of the Crescentic Technique.

Large Oscillating Saw Attachment (532.026)
The Large Oscillating Saw Attachment is a specially designed saw attachment for performing a crescentic saw cut, e.g. while performing a Tibial Plateau Leveling Osteotomy in the canine proximal tibia. The attachment is approved for use in both humans and animals.

Inserting the saw blade
Insert the saw blade in the saw blade coupling and tighten the screw in the saw blade with the key (532.027) that was delivered with the attachment or use a T15 StarDrive screwdriver (e.g. 314.115).

Check that the saw blade is correctly in place and properly tightened.

Mounting the saw attachment
Make sure that the mode switch of the handpiece is in the LOCK 🔒 position and that the locking sleeve on the saw attachment is set to the unlock position 🔓. Insert the saw attachment in any position into the attachment coupling of the handpiece until it locks into place. To prevent vibrations during operation and to increase the sawing capacity, additional manual tightening of the attachment onto the handpiece is required. Turn the locking sleeve into the lock direction until you feel that the coupling pins engage into the handpiece (approx. half a revolution).



Caution:
- Set the mode switch of the SED to the ON position. Never operate the Large Oscillating Saw attachment in the OSC DRILL mode (🎧).
- Avoid applying high pressure onto the saw blade.

Removing the saw attachment
Turn the locking sleeve to the unlock position 🔓 before pushing both release buttons on the handpiece.

Other Attachments

511.773 Torque Limiter 1.5 Nm
511.776 Torque Limiter 0.8 Nm
511.777 Torque Limiter 0.4 Nm

Coupling the Torque Limiter to the power tool
Torque Limiters are connected to the Small Electric Drive using the AO Quick Coupling (05.001.251).

Mounting and removing a screwdriver shaft
Insert the screwdriver shaft while rotating it slightly until it locks into place. To remove it, pull back the unlocking ring and pull out the screwdriver shaft.

Using the Torque Limiter
Pick up a screw from the corresponding LCP system (Locking Compression Plate) with the screwdriver shaft and insert it in the desired plate hole. To insert the screw, start the power tool slowly, increase the speed and then reduce it again before the screw is fully tightened. The torque is automatically limited to 1.5, 0.8 or 0.4 Nm. When this limit is reached, you will hear a distinct clicking. Stop the tool immediately and pull the tool away from the screw.

Follow the surgical technique of the respective LCP system.

Caution: The Torque Limiter must be annually serviced and recalibrated by Synthes. Note the information on the test certificate in the packaging. The user is responsible for following the calibration schedule.

General Information

Power tool units and attachments are frequently exposed to high mechanical loads and shocks during use and should not be expected to last indefinitely. Proper handling and maintenance help extend the useful life of surgical instruments.

Gentle care and maintenance with proper lubrication can substantially increase the reliability and life of the system components.

Synthes recommends annual servicing and inspection by the original manufacturer or its exclusive sales outlets. The manufacturer assumes no warranty for damages arising from improper use, neglected or unauthorized servicing.

Caution:
- Reprocessing must be performed immediately after each use.
- Cannulations, unlocking sleeves and other narrow sites require special attention during cleaning.
- Cleaners with pH 7 – 9.5 are recommended. The use of cleaners with higher pH values can – depending on the cleaner – cause the discoloration of the surface of aluminum and its alloys, plastics or compound materials and they should only be used considering the data regarding material compatibility according to its data sheet. At pH values higher than 11, the surfaces of stainless steel can also be affected. For detailed information about material compatibility, see "Material Compatibility of Synthes Instruments in Clinical Processing" at www.synthes.com/reprocessing.
- Follow the enzymatic cleaner or detergent manufacturer's instructions for use for the correct dilution concentration, temperature, exposure time and water quality. If the temperature and time are not specified, follow Synthes' recommendations. Devices should be cleaned in a fresh, newly-made solution.
- Detergents used on the products will be in contact with the following materials: stainless steel, aluminum, plastic and rubber seals.
- Synthes recommends using new sterile cutting tools for each operation.

Unusual Transmissible Pathogens
Surgical patients identified as at risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Dispose of the instruments used or suspected of use on a patient with CJD after surgery and/or follow the current national recommendations.

Important:
- The clinical processing instructions provided have been validated by Synthes for preparing a non-sterile Synthes medical device; these instructions are provided in accordance with ISO 17664:2004 and ANSI/AAMI ST81:2004.
- Consult the national regulations and guidelines for additional information. In addition, compliance with internal hospital policies and the procedures and recommendations of manufacturers of detergents, disinfectants and any clinical processing equipment is additionally required.
- It remains the responsibility of the processor to ensure that the processing performed achieves the desired result using the appropriate properly installed, maintained and validated equipment, materials and personnel in the processing unit. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Preparation Prior to Cleaning

Disassembly
Before cleaning, remove all the instruments, attachments and cables from the power tool.

Consoles may be wiped with a cloth.

Important: Never immerse the handpiece or attachments in aqueous solutions or in an ultrasonic bath, as this could decrease the service life of the system.

Assembly prior to mechanical/automated cleaning
After the manual pre-cleaning and before the mechanical/automated cleaning, put the Protective Cap (05.001.077) on the handpiece (05.001.175).

05.001.077

After the manual pre-cleaning and before the mechanical/automated cleaning, connect both sides of the Cable (05.001.021, 05.001.025) with the Seal Nipple (05.001.027).

05.001.027

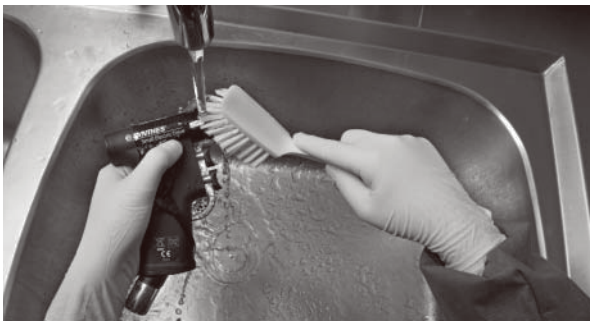
Note: The Protective Cap and the Seal Nipple are parts of the washing basket (68.001.630). You only need to order these two articles separately if you don't use this specially designed tray (05.001.077 for Protective Cap and 05.001.027 for Seal Nipple).

Handpieces and attachments may be processed using
a) manual cleaning and/or
b) automated cleaning with manual pre-cleaning.

Note: Clean all movable parts in opened position.

Manual Cleaning Instruction

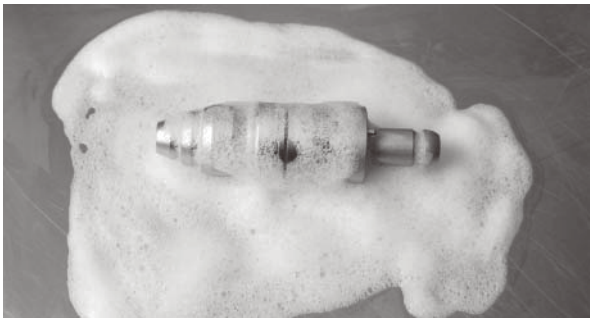
1. **Remove debris.** Rinse the device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft lint-free cloth or soft-bristled brush to assist in removing gross soil. For cannulations of the handpiece and attachments, the cleaning brush (519.40) should be used.



Note: Do not use pointed objects for cleaning.

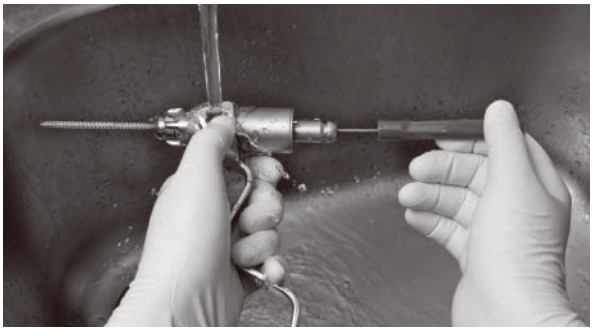
2. **Manipulate moving parts.** Manipulate all moving parts such as the triggers, sleeves and switches under running tap water to loosen and remove gross debris.

3. **Spray and wipe.** Spray and wipe the device using a neutral pH enzymatic solution for a minimum of 2 minutes. Follow the enzymatic detergent manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.

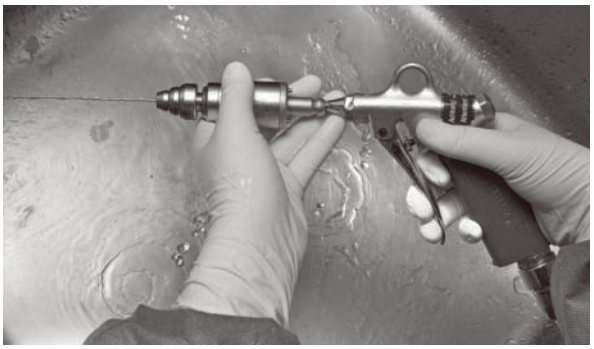


4. **Clean with detergent.** Clean the device manually under running warm water using an enzymatic cleaner or detergent for a minimum of 5 minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris.

   Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.



5. **Rinse with tap water.** Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other movable device features in order to rinse thoroughly under running water.



6. **Visually inspect device.** Inspect the cannulations, coupling sleeves, etc. for visible soil. Repeat steps 1 – 6 until no visible soil remains.

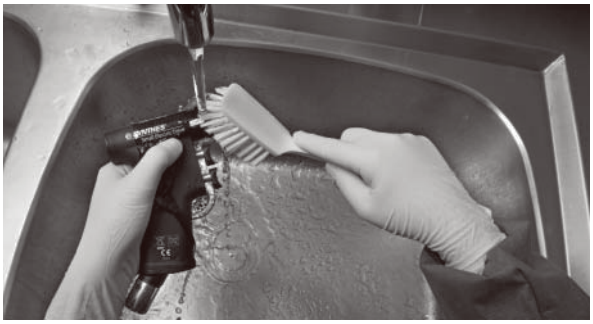
7. **Final rinse with de-ionized/purified water.** Final rinse with de-ionized or purified water for a minimum of 2 minutes.

8. **Dry.** Dry device using a soft lint-free cloth or clean compressed air.

Mechanical/Automated Cleaning Instruction with Manual Pre-cleaning

Important:
- Manual pre-cleaning prior to mechanical/automated cleaning/disinfection is important to ensure that cannulations and other difficult to access areas are clean.
- Alternative cleaning/disinfection procedures other than in the procedure described below (including manual precleaning) have not been validated by Synthes.
- After the manual pre-cleaning and prior to the mechanical/automated cleaning, ensure that the Protective Cap (05.001.077) is on the handpiece (05.001.175) and that both sides of the cable (05.001.021, 05.001.025) are connected with the Seal Nipple (05.001.027).

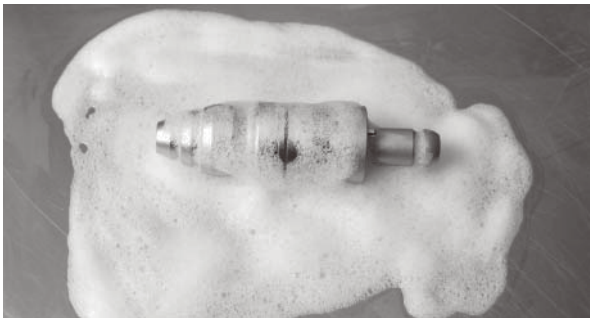
1. **Remove debris.** Rinse the device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft lint-free cloth or soft-bristled brush to assist in removing gross soil. For cannulations of the handpiece and attachments, the cleaning brush (519.40) should be used.



Note: Do not use pointed objects for cleaning.

2. **Manipulate moving parts.** Manipulate all moving parts such as the triggers, sleeves and switches under running tap water to loosen and remove gross debris.

3. **Spray and wipe.** Spray and wipe the device using a neutral pH enzymatic solution for a minimum of 2 minutes. Follow the enzymatic detergent manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.



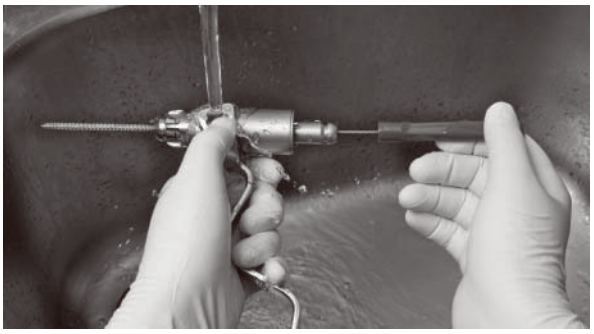
4. **Clean with detergent.** Clean the device manually under running warm water using an enzymatic cleaner or detergent for a minimum of 5 minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris.

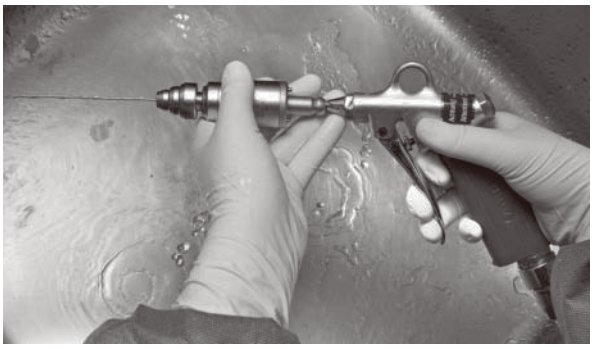
   Follow the enzymatic cleaner or detergent manufacturer's instructions for use for the correct temperature, water quality and concentration/dilution.

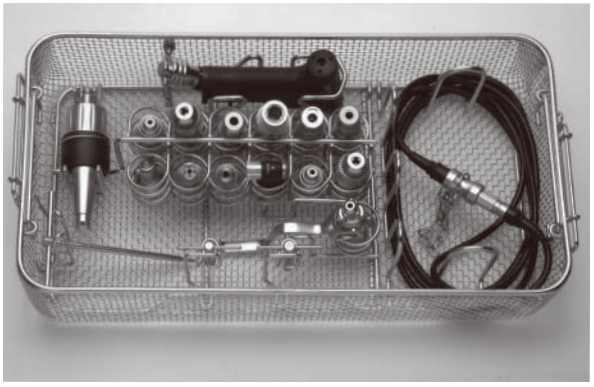
5. **Rinse with tap water.** Rinse the device thoroughly using cool to lukewarm running water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other movable device features in order to rinse thoroughly under running water.

6. **Visually inspect device.** Inspect the cannulations, coupling sleeves, etc. for visible soil. Repeat steps 1 – 6 until no visible soil remains.

7. **Load washing basket.** Place devices in the specially designed tray for machine washing supplied by Synthes (68.001.630). Ensure that all cannulations (handpiece and attachments), if applicable, are positioned vertically, i.e. in an upright position as shown.







68.001.630

Notes:

– Specific lid (68.001.602) is available for the washing basket.
– Before starting the mechanical/automated cleaning, put the Protective Cap on the handpiece (05.001.175) and connect both sides of the cable (05.001.021, 05.001.025) with the Seal Nipple. The protective cap and seal nipple is included in the washing basket (68.001.630) or sold separately.

8. Automated cleaning cycle parameters

Note: The washer/disinfector should fulfill the requirements as specified in ISO 15883.

Step	Duration (minimum)	Cleaning instructions
Rinse	2 minutes	Cold tap water
Pre-wash	1 minute	Warm water (≥ 40 °C); use detergent
Cleaning	2 minutes	Warm water (≥ 45 °C); use detergent
Rinse	5 minutes	Rinse with de-ionized (DI) or purified water (PURW)
Thermal disinfection	5 minutes	Hot DI water, ≥ 93 °C
Dry	40 minutes	≥ 90 °C

9. **Inspect the device.** Remove all the devices from the washing basket. Inspect the cannulations, coupling sleeves, etc. for visible soil. If necessary, repeat the manual pre-clean/automated cleaning cycle. Confirm that all parts are completely dry.

   Mechanical cleaning/disinfection is an additional stress for power equipment, especially for seals and bearings. Therefore, systems must be properly lubricated and regularly sent to be serviced (at least once per year).

Lubrication

The power tool and attachments should be regularly lubricated to ensure a long service life and smooth operation. It is recommended that the accessible moving parts of the handpiece, the lid and attachments are lubricated with 1 drop of Synthes autoclavable oil (519.97); distribute the oil by moving the components. Wipe off the excess oil with a cloth.

The following individual parts must be lubricated:

Handpiece (Fig. 1)
- Trigger shafts
- Attachment release buttons
- Attachment coupling
- Adjustment sleeve
- Lock slide

Attachments
All moving parts of all the attachments. Exception: the Radiolucent Drive (511.30) does not require lubrication.

Chucks (05.001.252 – 05.001.254)
Lubricate the jaws and toothed rim.

Open and close the drill chuck several times.

Quick Coupling for Kirschner Wires (05.001.186)
Lubricate the tension lever and clamping mechanism.

Hold the Quick Coupling up and add one drop of oil into the attachment hole and on the holder of the lever (Fig. 2). Move the tension lever several times.

Figure 1

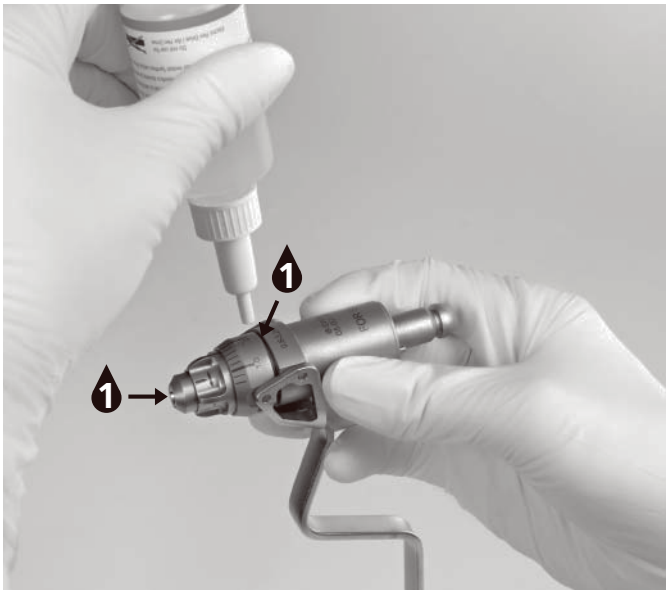


Figure 2

Mini Quick Coupling (532.011),
J-Latch Coupling (532.012),
AO Quick Coupling (05.001.250/05.001.251),
Large Quick Coupling (532.015),
Quick Coupling for Medullary Reaming
(532.017/532.018/532.019/532.020)
Lubricate the unlocking ring. Move it back and forth several times.

Figure 3

Oscillating Saw Attachment (532.021)
Lubricate the locking mechanism and saw blade coupling. Open and close the locking mechanism several times.

Oscillating Saw Attachment II (532.023)
Lubricate the unlocking sleeve, tool holder and attachment coupling. Move it back and forth several times.

Large Oscillating Saw Attachment (532.026)
First, lubricate and then move all the movable parts:
- Saw blade coupling (slot between the saw blade coupling and attachment)
- Locking sleeve of the attachment coupling (slots on both sides)
- Coupling pins
- Opening of the attachment coupling

Caution:
- To ensure a long service life and reduce repairs, the power tool and all attachments must be lubricated after each use. Exception: The Radiolucent Drive (511.30) does not require lubrication.
- The power tool and accessories may only be lubricated with Synthes special oil (519.97). The composition of the vapor-permeable and biocompatible oil is optimized for the specific requirements of the power tool. Lubricants with other compositions can cause the power tool to jam and be toxic.
- Only lubricate the power tool and attachments when clean.

Function Control

– Visually inspect for damage and wear.
– Check the handpiece controls for smooth operation and function.
– Check the coupling sleeves of the handpiece and attachments for smooth operation and check for function together with instruments such as cutting tools.
– Check instruments for correct adjustment and functioning prior to every use.

Packaging, Sterilization and Storage

Packaging
Place clean, dry products into the proper places in the Synthes case. Additionally, use an appropriate sterilization wrap or reusable rigid container system for sterilization, such as a Sterile Barrier System according to ISO 11607. Care should be taken in order to protect implants as well as pointed or sharp instruments from contact with other objects that may damage the surface or the Sterile Barrier System.

Sterilization

Note: Remove the Protective Cap from the handpiece. Remove the Seal Nipple from the cable.

Synthes Small Electric Drive System may be resterilized using validated steam sterilization methods (ISO 17665 or national standards). Synthes' recommendations for packed devices and cases are as follows

Cycle type	***Sterilization exposure time***	***Sterilization exposure temperature***	***Drying time***
Saturated steam-forced air removal (pre-vacuum)	Minimum 4 minutes	Minimum 132 °C Maximum 138 °C	20 – 60 minutes
	Minimum 3 minutes	Minimum 134 °C Maximum 138 °C	20 – 60 minutes

Drying times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.g., wraps or reusable rigid container systems), steam quality, device materials, total mass, sterilizer performance and varying cool down time.

Caution:
- The following maximum values may not be exceeded: 138 °C over a maximum of 18 minutes. Higher values can damage the sterilized products.
- Do not accelerate the cooling process.
- Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.

Storage
Storage conditions for products labeled "STERILE" are printed on the packaging label.

Packaged and sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests and extremes of temperature and humidity. Use products in the order in which they are received ("first-in, first-out principle"), taking note of any expiration date on the label.

Repairs and Technical Service

The tool should be sent to the Synthes office for repair if it is faulty or malfunctions. Contaminated products have to run through the complete reprocessing procedure before being sent to the Synthes office for repair or technical service.

Faulty devices may not be used. If it is no longer possible or feasible to repair the tool it should be disposed of, cf. the following section "Disposal".

Other than the above-mentioned care and maintenance, no further maintenance work may be carried out independently or by third parties.

Synthes recommends the device and accessories such as attachments to be regularly (once a year) serviced by the original manufacturer or an authorized site.

Caution: The manufacturer assumes no responsibility for damage resulting from neglected or unauthorized maintenance.

Disposal

Contaminated products have to run through the complete reprocessing procedure, so that there is no danger of infection in case of disposal.

In most cases, faulty tools can be repaired (cf. previous section "Repairs and Technical Service").

Please send tools that are no longer used to your local Synthes representative. This ensures that they are disposed of in accordance with the national application of the respective directive. The tool may not be disposed of with household waste.

Troubleshooting

Problem	Possible causes	Solution
Handpiece does not start up.	The console is not switched on or connected.	Connect and/or switch on the console.
	The handpiece is not connected to the console.	Connect the handpiece to the console.
	The adjustment sleeve on the handpiece is set to LOCK position 🔒.	Set the adjustment sleeve to ON or 🎧.
	The machine has not cooled down sufficiently following sterilization (overheating protection is activated).	Wait until the machine has cooled down.
	The tool was not cooled off after sterilization.	Let the tool cool to room temperature.
Machine stops suddenly.	The machine has overheated (overheating protection is activated).	Wait until the machine has cooled down.
Attachments cannot be coupled to the unit.	The attachment coupling is blocked by deposits.	Remove solid objects with a pair of tweezers. **Caution:** When removing objects, set the unit to LOCK 🔒.
Oscillating saw attachment vibrates too much.	The saw blade locking mechanism is not tight.	Tighten the locking knob of the saw blade coupling.
	The adjustment sleeve is set to 🎧.	Turn the adjustment sleeve to ON.
The Kirschner wire is inserted in the handpiece and cannot be moved forward.	The Kirschner wire was inserted from the rear.	Lock the machine. Remove the attachment, hold the drive shaft opening down and shake out the Kirschner wire.
Tool (saw blade, drill, burr etc.) can not be coupled or only with difficulty.	Shaft geometry of the tool is damaged.	Replace the tool or send it to your Synthes service office.
Bone and tool heat up during surgery.	Cutting edges of the tool are blunt.	Replace the tool.
LED on the console flashes.	The console is defective.	Send in the console to your Synthes service center.

System Specifications

The device meets the following standards
IEC 60601-1 / 60601-1-2 / 60601-1-4 /
61000-6-2 / 61000-6-4 Medical Electrical Equipment

UL 2601-1

With regard to electrical shock, fire, mechanical hazards, only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1

Environmental conditions

	Operation	Storage
Temperature:	10 – 40 °C 50 – 104 °F	–20 – 50 °C –4 – 122 °F
Relative humidity:	30 – 95%	10 – 95%
Atmospheric pressure:	700 – 1060 hPA 0.7 – 1.06 bar	500 – 1060 hPA 0.5 – 1.06 bar
Altitude:	0 – 5000 m	0 – 5000 m

	Transportation
Temperature:	–29 – 60 °C for max. 72 h –20 – 140 °F for max. 72 h
Relative humidity:	10 – 95%
Atmospheric pressure:	500 – 1060 hPA 0.5 – 1.06 bar

Duty Cycle:
Intermittent operation

		$X_{s\ on}$	$Y_{s\ off}$	Cycles
Drilling and tapping threads and reaming		120 sec	60 sec	10
Burring		60 sec	60 sec	3
Kirschner Wire setting		30 sec	60 sec	10
Sawing	532.021	30 sec	60 sec	6
	532.023	15 sec	60 sec	5
	532.026	30 sec	60 sec	5
Other attachments		120 sec	60 sec	10

Generally, electrical systems can heat up if in constant use. For this reason, the handpiece and the attachment should be allowed to cool for at least 60 seconds (Ys off) following the time of constant use (Xs on). After a certain amount of cycles (defined in the above table under "Cycles"), the handpiece and attachment should be allowed to cool for 30 minutes. If this is observed, the system will be prevented from overheating and possibly harming the patient or user. The user is responsible for the application and for turning off the system as prescribed. If longer periods of constant use are required, an additional handpiece and/or attachment should be used.

These recommendations for times of use for the attachments of the Small Electric Drive have been determined under average load with an ambient air temperature of 20 °C (68 °F). Depending on the cutting tool used and on the load applied, the heat generation of the handpiece, attachment and/or cutting tool can vary. Always control the temperature of the system to prevent overheating and possibly harming the patient or user.

Caution:
- Carefully observe the above recommended duty cycles.
- Always use new cutting tools to prevent the heating up of the system due to reduced cutting performance.
- Careful maintenance of the system will reduce heat development in the handpiece and the attachments.
- The Small Electric Drive must not be stored or operated in an explosive atmosphere.

Technical Data
Small Electric Drive (SED): 05.001.175

Degree of protection against the penetration of water:	IPX4
Degree of protection against electrical shock:	B
Cannulation:	3.2 mm
Weight:	537 g
Length:	90 mm
Noise level in the operating position:	approx. 65 dB(A)
Continuously variable speed (without attachment):	0–3150 rpm
Clockwise and counterclockwise running, oscillating running	

Consoles: 05.001.000 and 05.001.002

Operating voltage:	100–240 VAC, 50/60 Hz
Operating current:	2.0–0.7 A
Degree of protection:	IPX0

Console: 05.001.000

Weight:	5.4 kg		
Dimensions:	250 mm	155 mm	175 mm

Console: 05.001.002

Weight:	4.1 kg		
Dimensions:	250 mm	155 mm	125 mm

Technical data is subject to tolerances. Specifications are approximate and may vary from one device to another or as a result of power supply fluctuations.

Declaration of the emission sound pressure level and the power level according to the EU guideline 2006/42/EC Annex I

Measurements of the sound pressure level [LpA] are carried out in accordance with standard EN ISO 11202.

Measurements of the sound power level [LwA] are carried out in accordance with standard EN ISO 3746.

Information according to test protocol no.: 1711-5323/03.10, date of testing: 16–17 February 2011.

Handpiece	Attachment	Tool	Handpiece Sound Level (LpA) in [dB(A)]	Sound Power Level (LwA) in [dB(A)]	Max. daily exposure time without hearing protection
Small Electric Drive (05.001.175)	–	–	61	–	> 8 h
	AO Quick Coupling (05.001.250)	–	63	–	> 8 h
	Oscillating Saw Attachment (532.021)	Saw blade (532.045)	75	–	> 8 h
		Saw blade (532.067)	84	93	> 8 h
	Oscillating Saw Attachment II (532.023)	Saw blade (03.000.313)	81	89	> 8 h
		Saw blade (03.000.316)	83	92	> 8 h
	Large Oscillating Saw Attachment (532.026)	Saw blade (03.000.394)	85	95	8 h
		Saw blade (03.000.396)	84	94	> 8 h

Declaration of vibration emission according to the EU guideline 2006/42/EC Annex I

The assessment of the vibration emissions [m/s2] is to be made to the hand-arm system according to EN ISO 8662.

Information according to test protocol no.: 1711-5323/03.10, date of testing: 18 February 2011.

Handpiece	Attachment	Tool	Declaration [m/s²]	Max. daily exposure
Small Electric Drive (05.001.175)	–	–	< 2.5	No limitation
	AO Quick Coupling (05.001.250)	–	< 2.5	No limitation
	Oscillating Saw Attachment (532.021)	Saw blade (532.045)	vertical: < 2.5 horizontal: < 2.5	No limitation No limitation
		Saw blade (532.067)	vertical: 5.4 horizontal: 14.03	6 h 52 min 1 h
	Oscillating Saw Attachment (532.023)	Saw blade (03.000.313)	4.03	No limitation
		Saw blade (03.000.316)	5.68	6 h 8 min
	Large Oscillating Saw Attachment (532.026)	Saw blade (03.000.394)	12.71	1h 16 min
		Saw blade (03.000.396)	16.09	44 min

Accompanying Documents According to IEC 60601-1-2, 2007, Clause 6

Table 1: Emission

Guidance and manufacturer's declaration – electromagnetic emissions

The Synthes Small Electric Drive System is intended for use in the electromagnetic environment specified below.
The customer or user of the Synthes Small Electric Drive System should ensure that it is used in such an environment.

Emission test	***Compliance***	***Electromagnetic environment – guidance***
RF emissions CISPR 11	Group 1	The Synthes SED System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Synthes SED handpiece is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: Immunity (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity

The Synthes Small Electric Drive System is intended for use in the electromagnetic environment specified below.
The customer or user of the Synthes Small Electric Drive System should ensure that it is used in such an environment.

Immunity test standard	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) < 5% U_T for 5 s	< 5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) < 5% U_T for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the Synthes SED System requires continued operation during power mains interruptions, it is recommended for the Synthes SED System to be powered from an UPS.

Note: U_T is the AC mains voltage prior to the application of the test level.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	100 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer's declaration – electromagnetic immunity

The Synthes Small Electric Drive System is intended for use in the electromagnetic environment specified below.
The customer or user of the Synthes Small Electric Drive System should ensure that it is used in such an environment.

Electromagnetic environment – guidance

Portable and mobile RF communications equipment should be used no closer to any part of the Synthes Small Electric Drive System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	***IEC 60601 test level***	***Compliance level***	***Recommended separation distance***[a]
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 12 Vrms 150 kHz to 80 MHz	$d = 0.35 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 800 MHz to 2.5 GHz	E2 = 7 V/m 800 MHz to 2.7 GHz	$d = 0.35 \sqrt{P}$ 800 MHz to 2.7 GHz

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, [b] should be less than the compliance level in each frequency range.[c]

Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:
– At 80 MHz and 800 MHz, the higher frequency range applies.
– These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Possible shorter distances of outside ISM bands are not considered to have a better applicability of this table.

b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Synthes Small Electric Drive System is used exceeds the applicable RF compliance level above, the Synthes Small Electric Drive System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Synthes Small Electric Drive System.

c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 4: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the Synthes Small Electric Drive System

The Synthes Small Electric Drive System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Synthes Small Electric Drive System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Synthes Small Electric Drive System as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	***Separation distance according to frequency of transmitter*** m		
	150 kHz to 80 MHz $d = 0.35\ \varpi P$	80 MHz to 800 MHz $d = 0.35\ \varpi P$	800 MHz to 2700 MHz $d = 0.35\ \varpi P$
0.01	4 cm	4 cm	10 cm
0.1	12 cm	12 cm	32 cm
1	35 cm	35 cm	1 m
10	1.11 m	1.1 m	3.2 m
100	3.5 m	3.5 m	10 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Ordering Information

Drive unit

05.001.175	Small Electric Drive

Consoles

05.001.002	Basic Console for Electric Pen Drive and Small Electric Drive
05.001.000	Standard Console with Irrigation, for Electric Pen Drive and Small Electric Drive

Attachments

532.011	Mini Quick Coupling, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.012	J-Latch Coupling, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
05.001.250	AO Quick Coupling, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
05.001.251	Screw Attachment with AO Quick Coupling, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
05.001.252	Chuck (Drilling Speed), with Key, clamping range up to Ø 4.0 mm
05.001.253	Chuck (Drilling Speed), with Key, clamping range up to Ø 7.3 mm
05.001.254	Chuck (Reaming Speed), with Key, clamping range up to Ø 7.3 mm, with reverse motion
532.015	Quick Coupling for DHS/DCS triple reamers, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.017	AO Quick Coupling for Medullary Reaming, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.018	Hudson Quick Coupling for Medullary Reaming, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.019	Trinkle Quick Coupling, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.020	Trinkle Quick Coupling, modified, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
05.001.186	Quick Coupling for Kirschner Wires Ø 0.6 to 3.2 mm, for Small Electric Drive
05.001.187	Burr Attachment,for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.021	Oscillating Saw Attachment, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.023	Oscillating Saw Attachment II (Crescentic Technique), for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.026	Large Oscillating Saw Attachment, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
532.031	Adapter for Radiolucent Drive, for Nos. 532.001, 532.010, 532.101, 532.110 and 05.001.175
511.30	Radiolucent Drive
511.773	Torque Limiter, 1.5 Nm, for AO Quick Coupling
511.776	Torque Limiter, 0.8 Nm, for AO Quick Coupling
511.777	Torque Limiter, 0.4 Nm, for AO Quick Coupling

Cable

05.001.021	Cable for Electric Pen Drive and Small Electric Drive – Console, length 4 m
05.001.025	Cable for Electric Pen Drive and Small Electric Drive – Console, length 3 m
05.001.027	Seal Nipple for Cable, for Electric Pen Drive and Small Electric Drive

Accessories

68.001.252	Vario Case for Small Electric Drive
68.001.253	Vario Case for attachments for Small Battery Drive (II) and Small Electric Drive
689.507	Lid (stainless steel), size 1/1, for Vario Case
68.001.630	Washing Basket, size 1/1, for Small Electric Drive
68.001.602	Lid for Washing Basket, size 1/1
05.001.077	Protective Cap for Small Electric Drive
519.40	Cleaning Brush for Compact Air Drive, Power Drive, Small Battery Drive (II) and Small Electric Drive
519.97	Oil Dispenser with Synthes Special Oil, 50 ml
532.024	Cleaning Brush for Oscillating Saw Attachment II (532.023)
310.93K	Spare Key for Drill Chuck, clamping range up to Ø 4.0 mm
510.19	Spare Key for Drill Chuck, clamping range up to Ø 7.3 mm

Saw blades, sterile (for 532.021)

	Usable length (mm)	Width (mm)	Cut thickness (mm)
532.041S	15	6	0.4
532.042S	15	10	0.4
532.043S	15	16	0.4
532.044S	18	4	0.4
532.045S	22	8	0.4
532.046S	22	12	0.4
532.047S	31	6	0.4
532.048S	31	10	0.4
532.061S	27	6	0.6
532.062S	27	10	0.6
532.063S	27	14	0.6
532.064S	50	10	0.6
532.065S	50	14	0.6
532.066S	50	20	0.6
532.067S	50	27	0.6

Parallel saw blades, sterile (for 532.021)

	Length (mm)	Usable length (mm)	Width (mm)	Cut thickness (mm)
532.081S	47.1	25	12	90° cut, 2.0 mm shortening
532.082S	47.1	25	12	90° cut, 2.5 mm shortening
532.083S	47.1	25	12	90° cut, 3.0 mm shortening
532.084S	47.1	25	12	90° cut, 4.0 mm shortening
532.085S	47.1	25	12	90° cut, 5.0 mm shortening
532.091S	47.1	25	12	45° cut, 2.0 mm shortening
532.092S	47.1	25	12	45° cut, 2.5 mm shortening
532.093S	47.1	25	12	45° cut, 3.0 mm shortening
532.094S	47.1	25	12	45° cut, 4.0 mm shortening
532.095S	47.1	25	12	45° cut, 5.0 mm shortening

Saw blades, sterile (for 532.023)

	Usable length (mm)	Blade width (mm)	Cut thickness (mm)	Diameter (mm)
03.000.311S	26.5	13.3	0.60	18
03.000.312S	25	16.3	0.60	22
03.000.313S	30	17.9	0.60	18
03.000.316S	30	21.9	0.60	22
03.000.340S	7	12.0	0.38	70
03.000.341S	12	11.5	0.38	70
03.000.342S	12	9.5	0.38	70
03.000.343S	12	4.5	0.38	70

Saw blades, crescentic (for 532.026)

	Usable length (mm)	Radius (mm)	Cut thickness (mm)
03.000.390	45	12	0.60
03.000.391	45	15	0.60
03.000.392	45	18	0.60
03.000.393	45	21	0.60
03.000.394	45	24	0.60
03.000.395	50	27	0.60
03.000.396	50	30	0.60

Cutting tools

Detailed ordering information on the cuttings tools and burrs for the Small Electric Drive system with original size pictures can be found in the "Cutting Tools for the Electric Pen Drive" brochure.

Caution: Saw blades labeled "Single Use" should not be reused.

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